510(k) Summary MyLab90 Ultrasound Imaging System Esaote, S.p.A.

JUL 2 0 2005

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham, Official Correspondent The Anson Group 7992 Castleway Drive Indianapolis, Indiana 46250 Phone: (317) 849-1916 x103

Facsimile: (317) 577-9070

Contact Person:

Carri Graham

Date:

June 24, 2005

807.92(a)(2)

Trade Name:

(6100) MyLab90 Ultrasound Imaging System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse doppler imaging system 892.1550

Ultrasonic pulsed echo imaging system 892.1560

Classification Number:

90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

Esaote, S.p.A.	7250 Ultrasound Imaging System	K982444
Esaote, S.p.A.	7350 Ultrasound Imaging System	K050326
Esaote, S.p.A.	Technos Ultrasound Imaging System	K990360
Esaote, S.p.A.	Technos Ultrasound Imaging System	K014168
Esaote, S.p.A.	Technos Ultrasound Imaging System	K023255
Phillips, Inc.	iU22 Ultrasound Imaging System	K042540

807.92 (a)(4)

Device Description

The 6100 MyLab 90 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The 6100 is equipped with a CRT Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations.

The 6100 can drive phased (PA), convex (CA), linear array (LA) and Doppler probes. The 6100 is equipped with a DVD-RW disk drive that can be used for image storage. Data can also be stored directly to a Personal Computer via a LAN port. Optional accessory devices available for the 6100 include an S-VHS video recorder; a monochrome or color page printer. The 6100 is equipped with an isolation transformer to adequately insulate the system's peripherals.

807.92(a)(5)

Intended Use(s)

Esaote's MyLab90 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Adult Cephalic, Pediatric, Laparoscopic, Intraoperative: Abdominal, and Other: Urologic.

807.92(a)(6)

Techi	Technological Characteristics	tics			ייייים ב חבוונים
	6100 MyLab 90	Technos (Koon360, K014168 &	7350 MyLab 50 (K050326)	Megas (K982444)	(K042540)
	noissimons simi	K023255)	Esaote, S.p.A.	Esaote, S.p.A.	Philips
		Esaote, S.p.A.	***************************************	1ECK0601-1	IEC60601-1
Electrical Safety	IEC60601-1	IEC60601-1	1EC0001-1	T-ack 3 (Acquetic	Track 3 (Acoustic Output
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Output Display)	Display)
T TO A TO					
Indication for Use	VES	YES	YES	YES	YES
OB/Fetal	VES.	VES	YES	YES	YES
Abdominal	YES	VEC	ON	NO	YES
 Intraoperative: Abdominal 	YES	1 100	VES	YES	YES
Pediatric	YES	VES I ES	VES	YES	YES
Small organ	YES	100	VES	ΥES	YES
Neonatal Cephalic	YES	XES	VEC	ΥES	YES
Adult Cephalic	YES	VIEW CELL	VES	YES	YES
Cardiac	YES	163	VEC	VES	YES
 Transesophageal 	YES	YES	VES 1123	VES	YES
Transrectal	YES	YES	VES 1 E3	VES	YES
Transvaginal	YES	YES	VES	VES	YES
Peripheral Vascular	YES	YES	NO TES	NO.	YES
 Laparoscopic 	YES	YES	NO.	NO S	YES
Musculoskeletal (conventional	YES	YES	YES	Č	t
& superficial)		VIC	O	NO	YES
Other: Urological	YES	1 00			
Probe Technology			VEC	VES	A/N
Phased Array	YES	YES	100	VES	YES
 Linear Array 	YES	YES	VEC 1 ES	VES	YES
 Convex Array 	YES	1 ES	VES	VES	YES
Doppler Probes	YES	YES	1123	YES	N/A
Di Con	YES	NC			

	46 (w) x 23.5 (h) x 68 (d) cm				
	use position:				
	46 (w) x 23.5 (h) x 55 (d) cm	00(4) \$ 155(4) \$ 56(4) \$	00(w) x 100(ii) x 105(u) ciii	60(w) x 160(n) x 120(u) cm	Dimensions
N/A	portable position:	60(m) v 155(h) v 90(d) cm	140/h) × 104/d) cm	1/0/L) 100/L) 100/L] 100/L) 100/L] 10	Weight
N/A	79 kg	90 kg	140 kg	130 15	
	general purpose measmements	general purpose measurements	general purpose measurements	general purpose measurements	
N/A	Cardiac, Vascular, OB and	Cardiac, Vascular, OB and	Cardiac, Vascular, OB and	Cardiac, Vascular, OB and	M&A Capabilities
YES	YES	YES	YES	YES	VCR / Page Printer
N/A	Media Storage, Storage SCU	Media Storage, Storage SCU	Media Storage, Storage SCU	Media Storage, Storage SCU	DICOM Classes:
YES	YES	YES	YES	YES	Digital Archival Capabilities
NA	SVGA	SVGA	SVGA	SVGA	Display Standard
ויכו	LCD or CK1 (optional)	CRT	CRT	CRT	Display type
	Transvaginal	Transrectal, Transvaginal	Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal	Biopsy Intended Uses
N/A	Cenaral Durance Transpertal	D			Biopsy Guidance
					Processing
I ES	Z	NO	NO	YES	Intelligent Real-Time Image
S S	NO	YES	YES	YES	Tissue Velocity Mapping feature
N/A	2 5 MHz	2 - 8 MHz	2 - 12 MHz	2 - 12 MHz	CFM/Doppler Frequencies
N/A	2 - 10 MHz		1.5 - 16 MHz	1 - 16 MHz	Imaging Frequencies
YES	NC	NO	YES	YES	3D
YES	NO	NO	NO	YES	Compound Imaging
YES	NO	NO	YES	YES	VPAN
YES	NO	YES	YES	YES	TVM
153	NO	YES	YES	YES	CnTl
VEC					Amplitude Doppler (PD), TEI
YES	YES	YES	YES	YES	2D, M-Mode, PW, CW, CFM,
					Modes of operation
			Esaote, S.p.A.		
(K042540) Philips	(K982444) Esaote, S.p.A.	/350 MyLab 50 (K050326) Esaote, S.p.A	Technos (K990360, K014168 & K023255)	6100 MyLab 90 this submission	
il 22 hv Philins	Marie	77 FA 1.1 - L ZA		1	



JUL 2 0 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Esaote, S.p.A. % Ms. Carri Graham Consultant The Anson Group 7992 Castleway Drive INDIANAPOLIS IN 46250

Re: K051837

Trade Name: MyLab 90 Ultrasound Imaging Systems, Model 6100

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 5, 2005 Received: July 6, 2005

Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab 90 Ultrasound Imaging Systems, Model 6100, as described in your premarket notification:

Transducer Model Number

BS230	<u>LA532</u>
CA123	<u>LP323</u>
CA421	PA023
CA430	<u>PA121</u>
CA621	<u>PA122</u>
EC123	<u>PA230</u>
IOE323	<u>TEE022</u>
LA424	<u>TRT23</u>
LA522	<u>2 CW</u>
LA523	<u>5CW</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Mancy Chogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Mod. 6100

K051837 Mode of Operation Color Amplitude Color Clinical Application CWD Combined Other PWD Doppler Velocity Doppler В М Α (PW) (CW) (specify) (specify) (CFM) (PD) **I**maging Ophthalmic N (see N (see Note 1) Note 2) Ν N Ν N N N Fetal N (see N (see Note 1) Note 2) N N N Ν N N **Abdominal** N (see N (see Note 2) N N Note 1) N N N N Intraoperative (specify) Intraoperative Neurological N (see N (see Note 2) Ν N N Note 1) N N Ν **Pediatric** N (see N (see Note 2) N Ν Note 1) Ν N N N Small Organ (specify) N (see N (see Note 2) Note 1) N N N N N N **Neonatal Cephalic** N (see N (see Note 2) N Note 1) N Ν **Adult Cephalic** N N N N (see N (see Note 2) Ν Note 1) Ν Ν N N Cardiac N (see N (see Note 1) Note 2) Ν Ν Ν Ν N N Transesophageal N (see N (see Note 2) N N Note 1) N Ν Ν Ν Transrectal N (see N (see Note 2) Ν Ν N N N Ν Note 1) Transvaginal Transurethral Intravascular N (see N (see Note 2) N N N Ν Ν N Note 1) Peripheral Vascular N (see N (see Note 1) Note 2) N N N N Laparoscopic N Ν N (see N (see Muscolo-skeletal Note 1) Note 2) Ν Conventional Ν Ν N N (see N (see N Note 1) Note 2) Muscolo-skeletal Superficial N Ν Ν N N N (see N (see

Other (Urological) N N N N N
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional (Comments:
Small Orga	ins (thyroid, testicles, penis and breast);
	Vascular to include Vein Mapping & Scleroterapy
Intraoperat	ive (Abdominal)

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI (Contrast Media) 3D VPan

TVM (Tissue Velocity Mapping) Compound

Prescription Use	Division of Reproductive, Abdominal, and Radiological Devices K05/83%
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Note 1)

N

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Note 2)

BS230

					N	Node of Ope	eration			
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppier (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic					ļ					
Fetal										
Abdominal		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Intraoperative (specify)										
Intraoperative Neurological		ļ <u>-</u>	ļ							
Pediatric		ļ								ļ
Small Organ (specify)			ļ		<u></u>	ļ				ļ
Neonatal Cephalic		ļ							N (see	N (see
Adult Cephalic		N	N	· N	N	N	N		Note 1)	Note 2)
Cardiac		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)
Transesophageal			ļ	1		ļ				
Transrectal		ļ	<u> </u>					·		
Transvaginal		<u> </u>	ļ	<u> </u>	ļ	ļ			<u> </u>	
Transurethral		<u>.</u>	ļ			ļ				
Intravascular			<u> </u>	1					ļ	<u> </u>
Peripheral Vascular		<u> </u>	<u> </u>		<u> </u>					ļ
Laparoscopic		ļ		ļ						ļ
Muscolo-skeletal Conventional		<u> </u>		ļ	<u> </u>				<u> </u>	
Muscolo-skeletal Superficial	<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ			ļ		ļ
Other (Urological) N= new indication: P= previou			<u> </u>							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live;
, ,	B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
Note (2):	TEI (Tissue Enhanced Imaging) mode

CnTi (Contrast Media)
3D
VPan
Compound

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(Division Sign-Off)	7
Division of Reproductive, and Radiological Devices	. — -
510(k) Number	K001837

Prescription Use____

					N	fode of Op	eration			
Clinical Application	Α	В	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				-	<u> </u>			_		
Fetal									N (see	N (see
Abdominal		N	N	N	ļ	N	N		Note 1)	Note 2)
Intraoperative (specify)										
Intraoperative Neurological			<u></u>	ļ	<u> </u>				N (see	N (see
Pediatric		N	N	N		N	N		Note 1)	Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic		N	N	N	ļ	N	N		N (see Note 1)	N (see Note 2
Adult Cephalic		<u> </u>	ļ. <u></u>	ļ					N (see	N (see
Cardiac		N	N	N	ļ	N	N	<u> </u>	Note 1)	Note 2
Transesophageal	ļ		ļ				<u> </u>		<u> </u>	<u> </u>
Transrectal	ļ <u>.</u>	<u> </u>	ļ	ļ	ļ	ļ		 	ļ	<u> </u>
Transvaginal			<u> </u>	<u> </u>	<u> </u>	<u> </u>			<u> </u>	
Transurethral	ļ	<u> </u>		<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ		<u> </u>
Intravascular		<u> </u>		ļ		<u> </u>		ļ	1 1/2	N (see
Peripheral Vascular	<u> </u>	N	N	N	<u> </u>	N	N	<u> </u>	N (see Note 1)	Note 2
Laparoscopic Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial			<u> </u>					<u> </u>		
Other (Urological)					<u> </u>			<u> </u>	<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Small Organs (thyroid, testicles, penis and breast);

Peripheral Vascular to include Vein Mapping & Scienterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI/C³-Mode (Contrast Media) 3D

VPan Compound

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(Division Sign-Off) Division of Reprodu and Radiological De 510(k) Number	octive, Abdominal, evices/2057837

Prescription Use /

	Mode of Operation										
Fetal Abdominal Intraoperative (specify) Intraoperative Neurological Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic									N/ana	N (see	
Fetal		N	N	N		N_	N		N (see Note 1)	Note 2)	
		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
			<u> </u>								
			 -	<u> </u>	 						
Intraoperative Neurological			ļ	ļ					N (see	N (see	
Pediatric		N	N_	N_		N_	N		Note 1)	Note 2)	
Small Organ (specify)						ļ				 	
Neonatal Cephalic					<u> </u>		ļ				
Adult Cephalic				ļ						ļ	
Cardiac										<u> </u>	
Transesophageal					<u> </u>		ļ			ļ	
Transrectal		<u> </u>				ļ	<u> </u>			<u> </u>	
Transvaginal		<u> </u>					<u> </u>			<u> </u>	
Transurethral		<u> </u>				ļ <u>.</u>		<u> </u>	<u> </u>		
Intravascular								<u> </u>	<u> </u>	<u> </u>	
Peripheral Vascular		N	N	N		· N	N		N (see Note 1)	N (see Note 2	
Laparoscopic									1		
Muscolo-skeletal	1	1		7							
Conventional	 	+-	+-			-		 	 	┨	
Muscolo-skeletal Superficial	<u> </u>	 	1		1		<u> </u>	ļ	N (see	N (see	
Other (Urological)		N	N	N.		N	N	<u> </u>	Note 1)	Note 2	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional	Comments
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Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CnTl (Contrast Media)

3D VPan Compound

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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices KB 1837 510(k) Number

Prescription Use_____

	Mode of Operation										
Clinical Application	A	В	M	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic										A1 /	
Fetal		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Abdominal		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Intraoperative (specify)								<u></u>			
Intraoperative Neurological						ļ					
Pediatric				ļ			<u> </u>				
Small Organ (specify)			!		ļ	ļ	<u> </u>				
Neonatal Cephalic				<u> </u>						<u> </u>	
Adult Cephalic			<u> </u>	<u> </u>	<u> </u>					<u> </u>	
Cardiac			<u> </u>	ļ		<u> </u>	<u> </u>				
Transesophageal	ļ			<u> </u>	<u> </u>	ļ	ļ		ļ		
Transrectal	<u> </u>	ļ	ļ		ļ			<u> </u>	ļ	<u> </u>	
Transvaginal		<u> </u>	<u> </u>	<u> </u>	<u> </u>	_		<u> </u>	ļ	<u> </u>	
Transurethral		<u> </u>	ļ	ļ		_	ļ	ļ		<u> </u>	
Intravascular	<u> </u>		ļ			ļ	<u> </u>	`	N/222	N (and	
Peripheral Vascular		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Laparoscopic Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial	ļ <u>.</u>										
Other (Urological)						<u> </u>			<u> </u>	<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additio	nal Co	mments:

Peripheral Vascular to include Vein Mapping & Scienoterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI (Contrast Media)

3D **V**Pan

Compound

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
- Jik, Number

	Mode of Operation										
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic									Al /oo o	Nidaaa	
Fetal		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Abdominal		N	N	N		N	N_		N (see Note 1)	N (see Note 2)	
Intraoperative (specify)									<u> </u>		
Intraoperative Neurological					ļ	ļ—					
Pediatric				ļ	ļ						
Small Organ (specify)				ļ	<u> </u>	ļ	<u> </u>			ļ	
Neonatal Cephalic				<u> </u>	<u> </u>	ļ	ļ				
Adult Cephalic				<u> </u>						<u> </u>	
Cardiac					<u> </u>		<u> </u>				
Transesophageal				<u> </u>	<u> </u>						
Transrectal	<u> </u>				<u> </u>	ļ	ļ	ļ		ļ	
Transvaginal			<u> </u>	<u> </u>	ļ	ļ	ļ	ļ		ļ <u>.</u>	
Transurethral		<u> </u>	ļ	ļ	<u> </u>		<u> </u>			<u> </u>	
Intravascular			<u> </u>	<u> </u>	ļ	<u> </u>		<u> </u>	N/aaa	Al /cos	
Peripheral Vascular		N	N	N_	ļ	N	N		N (see Note 1)	N (see Note 2	
Laparoscopic				1	<u> </u>						
Muscolo-skeletal Conventional			1								
Muscolo-skeletal Superficial											
Other (Urological)		N	N	N		N_	N		N (see Note 1)	N (see	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Addi	ional	Comn	2tnar

Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI (Contrast Media)

3D VPan Compound

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(Division Sign-	Off)	7						
Division of Rep	(Division Sign-Off) Division of Reproductive, Abdominal,							
and Radiologic	al Devices	KD51837						
510(k) Number	ſ <u></u>	10001001						

Prescription Use_____

EC123

	Mode of Operation										
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic					ļ				Al (ann	N (see	
Fetal		N	N_	N_	ļ	N_	N		N (see Note 1)	Note 2)	
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)						ļ					
Neonatal Cephalic					ļ	ļ <u>.</u>					
Adult Cephalic			<u> </u>		ļ	ļ				<u> </u>	
Cardiac		ļ		ļ	<u> </u>	ļ					
Transesophageal						<u> </u>			1/4	N/	
Transrectal	<u> </u>	N	N	N		N	N		N (see Note 1)	N (see Note 2	
Transvaginal		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Transurethral										<u> </u>	
Intravascular		<u> </u>								<u> </u>	
Peripheral Vascular	ļ	<u> </u>						ļ	<u> </u>	ļ	
Laparoscopic		<u> </u>				ļ		<u> </u>			
Muscolo-skeletal Conventional					1	_				1	
Muscolo-skeletal Superficial											
Other (Urological)		N	N	N		N	N		N (see Note 1)	N (see	

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live
	B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
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VPan

Compound

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(Division Sign	Off)		4	
Division of Re	productive	e, Abdomiń	ial,	
and Radiologic			1027	
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					K	Mode of Ope	eration									
Clinical Application	Α	В	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)						
Ophthalmic						-				-						
Fetal																
Abdominal																
Intraoperative (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)						
Intraoperative Neurological				ļ		<u> </u>			N (see	N (see						
Pediatric		N	N	N		N	N		Note 1)	Note 2)						
Small Organ (specify)		N	N	N		N	N N		N (see Note 1)	N (see Note 2)						
Neonatal Cephalic				<u> </u>	ļ		<u> </u>	ļ								
Adult Cephalic			ļ	ļ	ļ			<u> </u>								
Cardiac		<u> </u>			<u> </u>	ļ. <u> </u>	ļ									
Transesophageal				ļ <u>.</u>						<u> </u>						
Transrectal				<u> </u>	<u> </u>	ļ	ļ			<u> </u>						
Transvaginal		ļ	<u> </u>	ļ	ļ	<u> </u>		<u> </u>		ļ <u> </u>						
Transurethral		<u> </u>		<u> </u>	<u> </u>	<u> </u>	ļ <u>-</u>	_		<u> </u>						
Intravascular		<u> </u>	ļ							1						
Peripheral Vascular		N	N	N	ļ	N	N	<u> </u>	N (see Note 1)	N (see Note 2)						
Laparoscopic Muscolo-skeletal		-							N (see	N (see						
Conventional	ļ	N	N	N	ļ	N	N	1	Note 1) N (see	Note 2) N (see						
Muscolo-skeletal Superficial	<u> </u>	N	N	N	ļ	N	N	1	Note 1)	Note 2)						
Other (Urological)	1		<u> </u>	addad was	<u> </u>											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:
Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scieroterap
Intraoperative (Abdominal)

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.
	TEI (Tissue Enhanced Imaging) mode

CnTl (Contrast Media) 3D VPan

Compound

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and Radiological	Devices	11051	8311
510(k) Number		RW 1	00,

		Mode of Operation								
Clinical Application	Α	В	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal					ļ		<u> </u>			
Abdominal					<u> </u>	<u> </u>				
Intraoperative (specify)						ļ			ļ.———	<u> </u>
Intraoperative Neurological									11/2-2	N (222
Pediatric		N	N	N		N	N	İ	N (see Note 1)	N (see Note 2)
Small Organ (specify)	-	N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic										ļ
Adult Cephalic					<u> </u>					ļ
Cardiac		ļ			<u> </u>			<u> </u>		-
Transesophageal		<u> </u>		<u> </u>		<u> </u>	ļ	ļ		
Transrectal			ļ	<u> </u>	<u> </u>	<u> </u>				
Transvaginal		-	ļ	ļ	<u> </u>		<u> </u>			
Transurethral	ļ		<u> </u>	<u> </u>	<u> </u>		 	-		<u> </u>
Intravascular	<u> </u>						<u>.</u>	ļ	N/sss	N (see
Peripheral Vascular		N	N	N		N_	N	<u> </u>	N (see Note 1)	Note 2
Laparoscopic			<u> </u>		<u> </u>		ļ		Nidaaa	N (see
Muscolo-skeletal Conventional		N	N	N_		N	N		N (see Note 1)	Note 2
Muscolo-skeletal Superficial		N	N	И		N	N		N (see Note 1)	N (see Note 2
Other (Urological)				addad un				<u> </u>		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Small Organs (thyroid, testicles, penis and breast);

Peripheral Vascular to include Vein Mapping & Scieroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CnTI (Contrast Media)

3D VPan Compound

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
R051832

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		Mode of Operation									
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic					ļ						
Fetal						ļ					
Abdominal						ļ			ļ		
Intraoperative (specify)							<u> </u>	_			
Intraoperative Neurological		<u> </u>	<u> </u>								
Pediatric		N	N_	N		N_	N_		N (see Note 1)	N (see Note 2)	
Small Organ (specify)		N	N	N		N_	N_		N (see Note 1)	N (see Note 2)	
Neonatal Cephalic											
Adult Cephalic										ļ	
Cardiac				<u> </u>						ļ	
Transesophageal		ļ <u>.</u>	ļ	ļ		<u> </u>			<u> </u>		
Transrectal			ļ		ļ					ļ	
Transvaginal		ļ	<u> </u>			<u> </u>			 	-	
Transurethral	ļ	<u> </u>	ļ		<u> </u>	<u> </u>				ļ	
Intravascular	 	ļ	<u> </u>	1			ļ		N/ass	N/coo	
Peripheral Vascular		N	N	N	ļ	N	N		N (see Note 1)	N (see Note 2)	
Laparoscopic			<u> </u>			ļ	ļ		<u> </u>	1 417	
Muscolo-skeletal Conventional		N	N	N		N _	N		N (see Note 1)	N (see Note 2)	
Muscolo-skeletal Superficial		N	N	N		N	N		N (see Note 1)	N (see Note 2	
Other (Urological) N= new indication; P= previou											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

<u>Small Organs (thyroid, testicles, penis and breast);</u>
<u>Peripheral Vascular</u> to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is five; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI (Contrast Media)

3D **VPan** Compound

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(Division Sign-Off) Division of Reproductive,	Abdominal,
and Radiological Devices 510(k) Number	K051837

		Mode of Operation								
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic						<u> </u>				
Fetal				ļ						
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Neonatal Cephalic					_					
Adult Cephalic					<u> </u>	ļ <u></u>	ļ		<u> </u>	
Cardiac					<u> </u>	ļ	ļ			ļ <u>.</u>
Transesophageal		ļ			ļ	<u> </u>		ļ	ļ	
Transrectal			ļ	ļ	ļ	<u> </u>				
Transvaginal					ļ <u> </u>	<u> </u>	<u> </u>		<u> </u>	
Transurethral			ļ .			ļ				ļ
Intravascular										
Peripheral Vascular		N	N	N		N	N	<u> </u>	N (see Note 1)	N (see Note 2)
Laparoscopic	<u> </u>						1			
Muscolo-skeletal				l N		N	N		N (see Note 1)	N (see Note 2)
Conventional	 	N	N	N N	+	N N	I N	 	Note I) N (see	Note 2
Muscolo-skeletal Superficial	ļ	N	N	N		N	N	ļ	Note 1)	Note 2
Other (Urological)				1						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:			
Small Omans (thyroid	testicles	penis	and

breast); Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CnTI (Contrast Media) 3D

VPan Compound

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(Division Sign-Off) Division of Reproductive, A	Abdominal,
and Radiological Devices 510(k) Number	W051837

	Mode of Operation										
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal				ļ		ļ	ļ <u>-</u>				
Abdominal					ļ		ļ				
Intraoperative (specify)				ļ							
Intraoperative Neurological	_										
Pediatric		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Small Organ (specify)		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Neonatal Cephalic							ļ				
Adult Cephalic		ļ	ļ	<u> </u>		<u> </u>				ļ	
Cardiac				<u> </u>					ļ		
Transesophageal			ļ		<u> </u>				<u> </u>		
Transrectal			ļ	<u> </u>	ļ	ļ	<u> </u>		ļ		
Transvaginal		ļ	ļ			<u> </u>	<u> </u>	<u> </u>		<u> </u>	
Transurethral	ļ		<u> </u>	<u> </u>	ļ	ļ	<u> </u>		ļ	-	
Intravascular		<u></u>									
Peripheral Vascular		N	N	N	ļ <u>.</u>	N	N		N (see Note 1)	N (see Note 2)	
Laparoscopic					<u> </u>						
Muscolo-skeletal Conventional										-	
Muscolo-skeletal Superficial	<u> </u>	<u> </u>		J		ļ					
Other (Urological)			<u> </u>	<u>l </u>	1					<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional	Comments:
	COLLEGE ILL.

Small Organs (thyroid, testicles, penis and breast);
Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CnTì (Contrast Media)

3D **V**Pan

Compound

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	Mode of Operation										
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic								_			
Fetal				ļ	ļ						
Abdominal				<u> </u>							
Intraoperative (specify)			<u> </u>								
Intraoperative Neurological						ļ	<u> </u>				
Pediatric											
Small Organ (specify)			<u> </u>								
Neonatal Cephalic					ļ						
Adult Cephalic					<u> </u>	ļ					
Cardiac						ļ					
Transesophageal					<u> </u>		<u> </u>				
Transrectal			ļ		<u> </u>	ļ	<u> </u>	ļ		ļ	
Transvaginal		<u> </u>	<u> </u>	ļ	<u> </u>		<u> </u>	ļ	ļ		
Transurethral	ļ	ļ	<u> </u>		<u> </u>	ļ	ļ <u>.</u>	ļ		ļ. <u> </u>	
Intravascular			<u> </u>								
Peripheral Vascular					<u> </u>	ļ		<u> </u>		N (===	
Laparoscopic Muscolo-skeletal Conventional		N	N	N		N	N		N (see Note 1)	N (see Note 2)	
Muscolo-skeletal Superficial											
Other (Urological)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination	n of the following modes: B+	M+PW+CW+CFM+PD,	where only one mode is live;
	B+CFM, M+CFM, B+PW, B+M	, B+CFM+PW where all sing	gle modes are live.	

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTl (Contrast Media)
3D
VPan

Compound

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(Division Sign-Off)	
Division of Reproductive, Abdominal,	
⊴⊓0 Radiological Devices	
510(k) Number K05/837	4.

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	Mode of Operation										
Clinical Application	Α	В	М	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic	:										
Fetal											
Abdominal				ļ					-		
Intraoperative (specify)			ļ								
Intraoperative Neurological									<u> </u>	N 2	
Pediatric		N	N	N	- N_	N	N		N (see Note 1)	N (see Note 2)	
Small Organ (specify)											
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)	
Adult Cephalic									ļ		
Cardiac		N	N	N	N	N _	N		N (see Note 1)	N (see Note 2)	
Transesophageal		ļ			ļ			ļ			
Transrectal		1	ļ					<u> </u>	ļ		
Transvaginal					ļ	<u> </u>					
Transurethral			<u> </u>	ļ							
Intravascular		<u> </u>	<u> </u>								
Peripheral Vascular		N	N	N	N	N_	N	ļ	N (see Note 1)	N (see Note 2)	
Laparoscopic Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial											
Other (Urological)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode CnTI (Contrast Media)

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VPan

TVM (Tissue Velocity Mapping)

Compound

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(Division Sign-Off) Division of Reproductive	ra Abdominal
and Radiological Device 510(k) Number	

	Mode of Operation										
Clinical Application	Α	8	М	PWO (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic					ļ				<u> </u>	<u> </u>	
Fetal								ļ	A1 /	N (see	
Abdominal		N_	N	N	N	N	N		N (see Note 1)	Note 2)	
Intraoperative (specify)								<u> </u>	<u> </u>		
Intraoperative Neurological					ļ					ļ	
Pediatric			ļ							ļ	
Small Organ (specify)					ļ <u>.</u>		<u> </u>			ļ	
Neonatal Cephalic					<u> </u>						
Adult Cephalic					 	<u> </u>	ļ		Nifees	N (see	
Cardiac		N	N	N	N	N	N	ļ	N (see Note 1)	Note 2)	
Transesophageal				<u> </u>	<u> </u>	ļ		ļ	ļ		
Transrectal			<u> </u>		<u> </u>	<u></u>	<u> </u>			ļ <u> </u>	
Transvaginal		<u> </u>	<u> </u>		<u> </u>		<u> </u>				
Transurethral		<u> </u>	ļ		<u> </u>	ļ				ļ	
Intravascular		<u> </u>			ļ <u>.</u>	<u> </u>			ļ <u>.</u>	 	
Peripheral Vascular			ļ						-	ļ	
Laparoscopic Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial										<u> </u>	
Other (Urological)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live:
	B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

B+CFM, M+CFM, B+PW, B+M, B+CFM
Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

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	Mode of Operation										
Clinical Application	Α	В	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic					ļ 						
Fetal											
Abdominal				ļ							
Intraoperative (specify)				ļ							
Intraoperative Neurological	<u>.</u>									11/1	
Pediatric	_	N	N	N	N	N_	N		N (see Note 1)	N (see Note 2)	
Small Organ (specify)			<u> </u>								
Neonatal Cephalic		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)	
Adult Cephalic						<u> </u>				11/	
Cardiac		N	N	N	N	N	N		N (see Note 1)	N (see Note 2)	
Transesophageal					<u> </u>			ļ	ļ	ļ	
Transrectal				<u> </u>			<u> </u>		<u> </u>	ļ	
Transvaginal		ļ		ļ	<u> </u>			<u> </u>	ļ	ļ	
Transurethral		<u> </u>]		ļ		<u> </u>	<u> </u>	ļ <u> </u>		
Intravascular		<u> </u>	<u> </u>		_	<u> </u>				11/2	
Peripheral Vascular		N	N	N	N.	N	N		N (see Note 1)	N (see Note 2)	
Laparoscopic										ļ	
Muscolo-skeletal Conventional											
Muscolo-skeletal Superficial									ļ		
Other (Urological) N= new indication: P= previous	ļ										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Peripheral Vascular to include Vein Mapping & Scleroterapy

Note (1): Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live; B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode

CnTl (Contrast Media)

3D

VPan

TVM (Tissue Velocity Mapping)

Compound

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Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal				<u> </u>	ļ			<u> </u>	N (see	N (see
Abdominal		N	N	N_	N_	N	N _		Note 1)	Note 2)
Intraoperative (specify)			<u> </u>		<u> </u>					
Intraoperative Neurological			<u> </u>							
Pediatric				ļ						
Small Organ (specify)				<u> </u>		ļ				
Neonatal Cephalic						ļ			11/222	N (see
Adult Cephalic		N	N_	N	N_	N.	N	<u></u>	N (see Note 1)	Note 2)
Cardiac		N	N	N	N	N_	N	ļ	N (see Note 1)	N (see Note 2)
Transesophageal		<u> </u>				ļ <u>.</u>				
Transrectal			<u> </u>		<u> </u>	ļ				<u> </u>
Transvaginal				ļ					<u> </u>	<u> </u>
Transurethral		ļ	<u> </u>	<u> </u>						<u> </u>
Intravascular									ļ	ļ
Peripheral Vascular			<u> </u>	ļ	1					<u> </u>
Laparoscopic Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial									ļ	
Other (Urological) N= new indication: P= previou									<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live;
	B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

B+CFM, M+CFM, B+PW, B+M, B+CFM
Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

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					ħ	tode of Ope	eration			
Clinical Application	Α	В	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal							<u> </u>	<u> </u>		<u> </u>
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological						<u> </u>				<u> </u>
Pediatric			·							
Small Organ (specify)										
Neonatal Cephalic			<u> </u>							
Adult Cephalic			ļ <u>.</u>		ļ	ļ		<u> </u>	N (see	N (see
Cardiac		N	N	N	N_	N	N		Note 1)	Note 2)
Transesophageal		N	N	N	N	N_	N	ļ	N (see Note 1)	N (see Note 2)
Transrectal		ļ <u>.</u>	ļ					<u> </u>	ļ	
Transvaginal	<u> </u>					<u> </u>		<u> </u>	<u> </u>	
Transurethral	<u> </u>	<u> </u>				<u> </u>			ļ	
Intravascular	ļ <u> </u>					<u> </u>	<u> </u>			<u> </u>
Peripheral Vascular			ļ <u> </u>	<u>.</u>	ļ			ļ <u></u>		<u> </u>
Laparoscopic	<u> </u>		<u> </u>		_					<u> </u>
Muscolo-skeletal Conventional				<u> </u>					<u> </u>	
Muscolo-skeletal Superficial										1
Other (Urological) N= new indication; P= previou	<u> </u>			<u> </u>						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live;
	B+CFM, M+CFM, 8+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan
TVM (Tissue Velocity Mapping)
Compound

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					N	lode of Ope	eration			
Clinical Application	Α	В	M	PWD (PW)	(CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal					<u> </u>		<u> </u>			
Abdominal							<u> </u>			
Intraoperative (specify)		<u> </u>	ļ						ļ	
Intraoperative Neurological					ļ					
Pediatric			<u> </u>			ļ	<u></u>			
Small Organ (specify)				<u> </u>	<u> </u>				ļ	
Neonatal Cephalic		<u> </u>	<u> </u>		<u> </u>					
Adult Cephalic		<u> </u>	<u> </u>			<u> </u>			ļ <u>.</u>	
Cardiac			<u> </u>			<u> </u>			<u> </u>	ļ
Transesophageal				l			<u> </u>	<u> </u>		11/222
Transrectal		N	N	N		N	N		N (see Note 1)	N (see Note 2)
Transvaginal										<u> </u>
Transurethral										
Intravascular						<u> </u>			ļ. <u></u> .	<u> </u>
Peripheral Vascular										
Laparoscopic										<u></u>
Muscolo-skeletal										1
Conventional	+		-	-		+	1	 	1	
Muscolo-skeletal Superficial	1_		<u> </u>					-	N (see	N (sec
Other (Urological)		l N	N	N		N	l N	1	Note 1)	Note 2

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note (1):	Combinations: any combination of the following modes: B+M+PW+CW+CFM+PD, where only one mode is live;
` '	B+CFM, M+CFM, B+PW, B+M, B+CFM+PW where all single modes are live.

Note (2): TEI (Tissue Enhanced Imaging) mode
CnTI (Contrast Media)
3D
VPan

Compound

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Clinical Application						Node of Ope	eration			
	Α	В	м	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				<u> </u>						
Fetal		ļ	ļ			ļ				i
Abdominal			ļ				<u> </u>			<u> </u>
Intraoperative (specify)					ļ	ļ				<u> </u>
Intraoperative Neurological			ļ			ļ. ——			ļ	
Pediatric			<u> </u>					ļ		
Small Organ (specify)			<u> </u>		ļ	<u> </u>				ļ <u>-</u>
Neonatal Cephalic			ļ						ļ	<u> </u>
Adult Cephalic		<u> </u>	<u> </u>					ļ	ļ	<u> </u>
Cardiac		<u> </u>	<u> </u>		N	ļ			ļ	<u> </u>
Transesophageal		_	<u> </u>						<u> </u>	<u> </u>
Transrectal		<u> </u>	<u> </u>			<u> </u>			ļ	-
Transvaginal			ļ	<u> </u>	 			<u> </u>	<u> </u>	
Transurethral	ļ	ļ	ļ					ļ. _	<u> </u>	<u> </u>
Intravascular		<u> </u>	ļ		ļ			-		ļ
Peripheral Vascular	<u> </u>	<u> </u>	_			-		<u> </u>	<u> </u>	
Laparoscopic Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial					<u> </u>				<u> </u>	<u> </u>
Other (Urological)	<u> </u>	<u> </u>			<u> </u>		<u> </u>			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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510(k) Number	KU3/831

Clinical Application	Mode of Operation									
	Α	₽	М	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		ļ		<u> </u>	ļ <u> </u>			<u> </u>		
Abdominal					ļ					
Intraoperative (specify)						ļ . <u></u>			<u> </u>	<u> </u>
Intraoperative Neurological			<u> </u>					_	.	:
Pediatric			<u> </u>			ļ				
Small Organ (specify)			ļ					ļ	<u> </u>	
Neonatal Cephalic			<u> </u>	<u>. </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>	
Adult Cephalic		<u> </u>	ļ				<u> </u>	ļ	ļ	ļ
Cardiac	<u> </u>		ļ		<u> </u>					
Transesophageal	<u> </u>		ļ		<u> </u>	ļ			ļ	<u> </u>
Transrectal	<u> </u>	_						<u> </u>	<u> </u>	<u> </u>
Transvaginal				_	ļ	<u> </u>				<u> </u>
Transurethral	<u> </u>	ļ. <u></u> .						<u> </u>	ļ	<u> </u>
Intravascular	ļ	<u> </u>					ļ			1-
Peripheral Vascular	<u> </u>				N		<u> </u>			
Laparoscopic Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial							1	<u> </u>	<u> </u>	<u> </u>
Other (Urological)				<u> </u>		die E		<u> </u>	<u></u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Peripheral Vascular to include Vein Mapping & Scleroterapy

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